K112727 (113)

JAN 13 2012

6. 510(k) Summary

Manufacturer:	Medical Facets NC LLC 1669 Federal Ave. Gastonia, NC 28052
Date:	September 15, 2011
Submitted by:	Medical Facets NC LLC
Company Contact	Glenn A. Rupp, President 1669 Federal Ave. Gastonia, NC 28052 (704) 562-7494 (704) 853-2105 (FAX)
US Agent Information	Orgenix LLC Mr. Donald W. Guthner 111 Hill Road Douglassville, PA 19518 +1-646-460-2984 +1-484-363-5879 (FAX)
Classification Name:	Screw, Fixation Bone; Pin, Fixation Smooth or Threaded
Common/Usual Name:	Bone Fixation Screws and Pins
Proprietary Name:	Medical Facets Cortical Screws Medical Facets Cancellous Screws Medical Facets Headless Compression Screws Medical Facets External Fixation Screws Medical Facets Pins and Guide Wires
Performance standards:	The *Medical Facets Cortical Screws, Medical Facets Cancellous Screws, Medical Facets Headless Compression Screws, Medical Facets External Fixation Screws, and Medical Facets Pins and Guide Wires* were mechanically tested to the following standards – ASTM F543, ASTM 1264, ASTM F2193 and ASTM F1541 (current versions).
Classification no.:	21CFR 888.3040 HWC, JDW, HTY Class II 87/Orthopedic Panel

Substantial Equivalence: Substantial equivalence for *Medical Facets Cortical Screws, Medical Facets Cancellous Screws, Medical Facets Headless Compression Screws, Medical Facets External Fixation Screws, and Medical Facets Pins and Guide Wires* is based on the similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices cleared under the following submissions:

- K083912 Treu Instrumente GmBH Bone Fixation Screws and Pins
- K090047 Synthes 1.5 Mini Fragment LCP System
- K911505 Simpex, Inc. Fixation Wire
- K051605 SBI K-wires

Predicate Devices: The subject device is substantially equivalent to similar previously cleared devices.

Device Description:

Medical Facets Bone Screws are available in thread diameters ranging from 1.5mm to 7.3mm, lengths ranging from 6mm to 180mm, and either solid or cannulated, and made of stainless steel or titanium.

Medical Facets External Fixation Screws are available in thread diameters ranging from 4mm to 6mm, lengths ranging from 60mm to 250mm, and thread lengths ranging from 18mm to 80mm, and made of stainless steel or titanium.

Medical Facets Kirschner Wires are available in wire diameters ranging from 1.0mm to 2.5mm, in lengths ranging from 100mm to 150mm, 0.028 inches to 0.062 inches, in lengths ranging from 4.0 inches to 12.0 inches and are partially or completely threaded, or smooth. Made of stainless steel or titanium.

Medical Facets Guide Wires are available in wire diameters ranging from 0.8mm to 2.8mm, in lengths ranging from 100mm to 450mm, are partially threaded or smooth. Made of stainless steel, titanium, or cobalt.

Medical Facets Steinmann Pins are available in wire diameters ranging from 0.078 inches to 0.187 inches, in lengths ranging from 9.0 inches to 12.0 inches, are completely threaded, or smooth. Made of stainless steel or titanium.

Intended Use: The *Medical Facet Bone Fixation Screws and Pins* are intended to be used as fixation implants for bone fractures, joint fusion, bone reconstruction, or as guide pins for insertion of other implantable devices.

Summary of Technological Characteristics	The *Medical Facet Bone Fixation Screws and Pins* are manufactured in Stainless Steel, Titanium and Cobalt (guide wires only).
Non-Clinical Testing	The *Medical Facet Bone Fixation Screws and Pins* were tested (worse case) according to the following standards: ASTM F543 - Standard Specification and Test Methods for Metallic Medical Bone Screws ASTM F2193 - Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System ASTM F1264 - Standard Specification and Test Methods for Intramedullary Fixation Devices ASTM F1541 - Standard Specification and Test Methods for External Skeletal Fixation Devices Test results indicated substantial performance of the worse case in side-by-side testing with the predicate device.
Conclusion	The information discussed above demonstrates that the *Medical Facet Bone Fixation Screws and Pins* are effective and perform as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medical Facets NC LLC
% Mr. Glenn A. Rupp
President
1669 Federal Avenue
Gastonia, North Carolina 28052

JAN 13 2012

Re: K112727
Trade/Device Name: Medical Facets Cortical Screws
Medical Facets Cancellous Screws
Medical Facets Headless Compression Screws
Medical Facets External Fixation Screws
Medical Facets Pins and Guide Wires
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastner
Regulatory Class: II
Product Code: HWC, JDW, HTY
Dated: December 15, 2011
Received: December 16, 2011

Dear Mr. Rupp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112727 (1/1)

5. Indications for Use

510(k) Number (if known): _____

Device Name: Medical Facets Cortical Screws
Medical Facets Cancellous Screws
Medical Facets Headless Compression Screws
Medical Facets External Fixation Screws
Medical Facets Pins and Guide Wires

The *Medical Facet Bone Fixation Screws and Pins* are intended to be used as fixation implants for bone fractures, joint fusion, bone reconstruction, or as guide pins for insertion of other implantable devices

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112727